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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,270	03/12/2004	Michael P. Wallace	30-7038142001 04-049 (US0)	7229
7590 01/09/2006			EXAMINER	
Bingham McCuthen, LLP Suite 1800 Three Embarcadero San Francisco, CA 94111-4067			PATEL, JOY	
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			3766	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/799,270	Applicant(s) WALLACE ET AL.	
	Examiner Joy P. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 10-17, 19, 21, 24, 26, 32-35, 38-43 and 45-47 is/are rejected.
7) ☒ Claim(s) 7-9, 18, 20, 22, 23, 25, 27-31, 36, 37 and 44 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 3/07/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 5, 10-15, 32-34, 38-43, 45, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma et al. (US 6,205,361).
2. In regard to claims 1, 32, and 45, Kuzma discloses, "...the electrode array, 10 (Figure 1), is made in the form of a silicone paddle having a number of electrode contacts..." (Column 3, lines 30-31). Kuzma further discloses that the "electrode contacts are typically wound around a shape-memory element, 12..." (Column 3, lines 42-43). Kuzma also adds: "The memory element, 12, is flexible or resilient, so that it can be folded or bent to another shape as desired or needed, but in the absence of an external folding or bending force, assumes the open, paddle shape shown in Figure 1" (Column 3, lines 50-54). Kuzma also discloses, "The space between the cylindrical edge portions 16 of the paddle array 10 is filled

with a thin silicone web or membrane 14" (Column 3, lines 56-57). This indicates that the spring layer (12) has a higher stiffness than the silicone web (14). The Examiner considers the "resilient skeletal spring layer" to include the shape-memory element 12, along with its insulative coating 16. The Examiner also considers element 14 to be "an insulative body having a planar region" From figure 1, it can be seen that this "resilient skeletal spring layer" is on the outer surface of the "insulative member" 14, since it is in contact with and surrounds the silicone web on all of its outer edges.

3. In regard to claims 2 and 33, Kuzma discloses, "The memory element 12 is flexible or resilient, so that it can be folded or bent to another shape as desired or needed, but in the absence of an external folding or bending force, assumes the open, paddles shape shown in FIG. 1" (Column 3, lines 50-54). Since the memory element 12, which is a portion of the "resilient skeletal spring layer" is flexible and can be bent, the insulative membrane (14), must also be flexible and flaccid, so that it can move with the "resilient skeletal spring layer".
4. In regard to claims 3 and 34, see figure 1, element 14. The Examiner considers this shape to be paddle shaped.
5. In regard to claim 5, see rejection for claim 2. Also see Figure 1, elements 12 and 16.
6. In regard to claim 10 and 38, Kuzma discloses, "In accordance with yet another aspect of the invention, the electrode array includes a membrane as an integral part thereof that prevents ingrowth of tissue inside the electrode array, thereby

facilitating repositioning, removal, and/or reinsertion of the electrode array as required.” (Column 1, lines 65-68; Column 2 lines 1-2; See also Column 3, lines 55-57).

7. In regard to claim 11 and 39, Kuzma discloses, “A paddle-type electrode or electrode array is implantable like a percutaneously inserted lead, i.e., without requiring major surgery, but once inserted, expands to provide a platform for many electrode configurations”. (Abstract, lines 1-4). Also see rejection for claim 2.
8. In regard to claims 12 and 40, Kuzma discloses, “In order to implant the electrode array, the needle (30) with electrode array (10) and insertion tool (20) inside, is inserted into the spinal cord cavity” (Column 4, lines 44-45). It is well known in the art that the “spinal cord cavity” is the epidural space as is seen in US Applications such as 10/691859 and 10/131980 and US Patent 6,754,539, among others.
9. In regard to claims 13 and 41, Kuzma discloses, “In order to implant the electrode array, the hollow tube or needle (with the folded or compressed electrode array therein) is injected into the living tissue of the desired implant site. The folded electrode array is then expelled from the hollow tube and allowed to assume its expanded or unfolded state within the tissue” (Column 2, lines 18-22).

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10. In regard to claims 14, 15, 42, and 43, Kuzma discloses, "In a preferred embodiment, such electrodes (11) comprise deployable, paddle-type, multicontact electrodes useful for spinal stimulation" (Column 1, lines 9-11).
11. In regard to claim 47, the spring element is in a laminar or layered relationship with the insulative body. From figure 1, it can be seen that there is a layered or "laminar" relationship between the spring element and the insulative member. By viewing figure 1, from left to right, one observes, element 16, followed by element 12, followed by element 16, followed by element 14, followed by element 16, followed by element 12, and finally followed by element 16 once again. The Examiner considers this to be a "laminar relationship".
12. Claims 16, 17, 19, 24, 26, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Partridge et al. (US 6,842,648).
13. In regard to claims 16 and 19, Partridge discloses, "The lead 1100 includes a lead body 1115, an elongate conductor 1116 contained within the lead body 1115, and at least one electrode assembly 1130" (Column 11, lines 34-36; See also figure 11a). Partridge further discloses, "The lead body 1115 is covered by a biocompatible insulating material" (Column 11, lines 41-42). The examiner considers the lead body with the insulative coating to be the "insulative membrane" which has a longitudinal axis. It can be seen from figure 11a that the electrode assembly 1130 is "associated" with the "insulative member". Partridge further discloses, "The conductor 116 comprises, in one embodiment, a

coil...The spirally coiled spring construction of the conductor also permits a substantial degree of elongation, within the elastic limits of the material..."

(Column 6, lines 24-31). Partridge further discloses, "Disposed within each of the tines 1220 is a conductive element 1221 formed of a conductive material, for example, a metal wire...The conductive element 1221 is electrically coupled with a conductor coil 1215, for instance, by welding, crimping, or by conductive adhesive. In addition, the conductive element 1221 is electrically coupled with the conductive member 1234 and forms the electrical connection between the conductive member 1234 and the conductor coil 1216, which allows for the tines 1220 to be conductive. Therefore, the examiner considers the main conductive coil 1216 to be the "resilient spring element" and the attached conductors 1221 to be the branches, since they are connected to the main coil 1216. The shape of the lead with the insulative coating is also considered to be tube shaped.

14. In regard to claim 17, Partridge discloses, "A conductor coil is capable of withstanding constant, rapidly repeated flexing" (Column 6, lines 25-26). Partridge further discloses, "The lead body 115 is covered by a biocompatible insulating material. Silicone rubber or other insulting material is used for covering the lead body 115" (Column 6, lines 20-23). Since the conductor is located within the lead body, the silicone rubber covering the lead body would also have to be soft or "flaccid" and flexible in order to accommodate the movement of the coil conductor.
15. In regard to claim 24, see figure 12.

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16. In regard to claim 26, Partridge, as discussed above, discloses that the lead is covered in silicone, a material that is well known in the art to be inert to the body.
17. In regard to claim 46, Partridge discloses, "The lead 1100 includes a lead body 1115, an elongate conductor 1116 contained within the lead body 1115, and at least one electrode assembly 1130" (Column 11, lines 34-36; See also figure 11a). Partridge further discloses, "The lead body 1115 is covered by a biocompatible insulating material" (Column 11, lines 41-42). Therefore, it can be seen that there is a "laminar" or layered relationship between the spring element and the insulative member. By viewing a cross-section of the lead (element 1115 in figure 11a), one would see a layer of insulation, followed by the conductor or "spring element", followed by another layer of insulation. Therefore, the Examiner considers this to be a "laminar relationship".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 4 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. in view of Gerber et al. (US 2001/0025192 A1). Kuzma is discussed above. Gerber teaches, "The lead body (115) is formed of a non-conductive, body compatible, flexible, outer tubular sheath (260)...." (Paragraph 54, lines 3-6; Figures 8 and 9). The invention disclosed in this application is "...an implantable medical lead having at least one stimulation electrode wherein the lead is implanted near sacral nerves for stimulation of a bundle of sacral nerve fibers." (Paragraph 3, lines 3-6). Furthermore, Gerber discloses, "The distal electrode array segment (160) can be percutaneously introduced..." (Paragraph 59, lines 5-7). Gerber also discloses, "But too close or tight a contact of the electrode with the sacral nerve can also cause inflammation or injury to the nerve diminishing efficacy and possibly causing patient discomfort (Paragraph 14, lines 16-29). Furthermore, Gerber discloses, "...the lead can allow for some movement of the lead without deteriorating the capture of the sacral nerves. Because the electrode does not need to be in direct contact with the nerve fibers and due to the large electrode area, a small amount of movement from the original implant position does not reduce the nerve capture (Paragraph 24, lines 3-8). In view of these teachings, it would be obvious to one skilled in the art to modify the Kuzma medical lead to have a tubular insulative membrane in order to prevent patient discomfort and injury to the nerves being stimulated.

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19. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma in view of Cross et al. (US 2003/0204228).
20. In regard to claims 6 and 21, Cross teaches, "In another embodiment, the paddle is curved about a vertical axis to substantially match the shape of a human spinal cord dura mater to help reduce lead migration." (Abstract, lines 9-12) (Also see paragraph 29, lines (1-4). In view of this teaching, it would be obvious to one of ordinary skill in the art to modify the Kuzma medical lead in order to match the shape of the human spinal cord dura mater and thereby reduce lead migration.

Allowable Subject Matter


Claims 7-9, 18, 20, 22, 23, 25, 27-31, 36, 37, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent examiner
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